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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,277	05/29/2001	Lars Peter Klitnose	P200000067	5508

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PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
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NEW YORK, NY 10036

EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3751

DATE MAILED: 09/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary

Application No.

09/867,277

Applicant(s)

KLITMOSE, LARS PETER

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is cooperation of the replaceable modules with the basis module is unclear.

Claim 4 recites the limitation “said medication cartridge” in line 2. It is unclear whether the “medication cartridge” is part of the invention or not.

Claim 6 recites the limitation “said movable wall” in line 4. There is insufficient antecedent basis for this limitation in the claim. It appears that claim 6 should depend from claim 4 to rectify this error.

Claim 10 recites the limitation “said means for holding medication cartridge” in line 4. There is insufficient antecedent basis for this limitation in the claim. It appears that claim 10 should depend from claim 2 to rectify this error.

Claim 15 recites the limitation “the user” in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 20 recites the limitation “further comprising the step of repeating steps.” It is unclear what steps are being repeated in the claimed method. Drawing reference elements should be utilized only for guidance purposes and cannot be used as a substitute for claimed subject matter.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-4, 6, 8, 9, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Howson et al.

Howson et al. disclose a drug delivery device 11 with a delivery unit 14, a basis module 50 with an electronic controller 56 and a replaceable cartridge or module 18 and sensors 64 which cooperate with basis module 50 to provide a specific function, such as drug delivery (Figure 1, col. 6, lines 22-26 and lines 29-31, col. 8, lines 13-14 and lines 58-63, col. 9, lines 10-19 and col. 17, lines 1-9) via syringe 54. Electronic controller 56 performs housekeeping or function checks (col. 9, lines 31-34) and can receive input from the user (Figure 4 and col. 9, lines 1-9).

Howson et al. further disclose in an embodiment that delivery unit 14 has a medication cartridge or syringe 1, 2, 3 or 4 with associated drivers 1, 2, 3, and 4 for delivery of medication to a user or patient (Figure 3 and col. 8, lines 13-25). The drivers 1, 2, 3 and 4 are controlled by module 50 that communicates with the patient and the logic cartridge or replaceable module 18. Further, each driver 1, 2, 3 or 4 depresses the plunger or piston rod of the corresponding disposable syringe to dispense medication (col. 8, lines 21-25). Module 50 also has a memory 58 to store data (col. 8, lines 58-68). Howson et al. also shows a display unit 68 in the delivery unit 14 (Figure 4 and col. 9).

Although Howson is silent about a means for supplying energy, a source of electrical energy is inherent to a system with electrical components such as electronic controllers and drivers.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howson et al., as applied to claims 1, 2 and 4, in view of Brown.

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Regarding claim 5, Howson et al. does not disclose that disposable syringe 54 (Figure 1) is connected to a replaceable catheter.

It is well known to use a catheter to transfer medication from a delivery device such as a syringe to a patient. For example, Brown teaches a catheter system with catheters 34 and 40 to deliver medication from a drug cartridge 20 to a patient (Figure 1 and col. 4, lines 32-50).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized a catheter with the delivery unit 14 of Brown to transfer medication from syringe 54 to the patient.

Regarding claim 7, Howson et al. disclose that drug delivery device 11 may be worn by a patient (col. 4, lines 57-66).

Howson et al. do not disclose any specific structure to contain the various components of their drug delivery device.

Brown teaches a housing 11 to contain a drug infusion device 10, medication cartridge 20, a controller 96 and a battery or source of electrical energy 94 (Figures 2, 7, and 8, col. 7, lines 51-60, col. 8, lines 48-50 and lines 66-67).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a housing 11 as taught by Brown in the drug delivery device of Howson et al. for containment of the various components to make the device compact or wearable by a patient.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Howson et al., as applied to claim 3, in view of Kovelman.

Howson et al. do not disclose that an item of information can be placed on the disposable or replaceable medication syringes. Further, Howson et al. do not disclose that their drug delivery device has a means for processing an item of information placed on a disposable or replaceable medication syringe.

Kovelman teach an information providing means 5 coupled to a medication cartridge 3 wherein the information providing means, for example a bar code disposed on an exterior surface of the medication cartridge, is further operatively coupled to an electronic delivery device 1 to control electronic delivery device 1 and to improve the performance of the electronic delivery

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device 1 (Figure 6, col. 1, lines 27-38 and lines 63-67, col. 2, lines 1-3 and lines 11-15 and col. 3, lines 1-6 and lines 49-54).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided an information providing means, as taught by Kovelman, on the medication cartridges or syringe 54 of Howson et al. such that said information providing means is operatively coupled to the driver to improve the performance of the drug delivery unit 14.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Howson et al. in view of Cooper.

Howson et al. does not disclose replaceable covers.

Cooper teaches replaceable covers for medical devices to provide comfort and enhanced appearance (col. 1, lines 58-65).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided replaceable covers as taught by Cooper on the device of Howson for enhanced appearance.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Howson et al. in view of Blomquist et al.

Howson et al. do not disclose a lock-out feature for their drug delivery device.

Blomquist et al. teach a drug delivery device with a pump 12 having a user input interface or keyboard 24 and a medication cassette or cartridge 16 (Figure 1 and col. 3, lines 27-34). Blomquist et al. further teach that keyboard 24 could have lock-out feature so that access is available to a specific user.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a lock-out feature in the keyboard of calculator 32 in the drug delivery device of Howson et al. to restrict access to a specific user.

Claims 13, 16-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howson et al. in view of Eggers et al.

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Regarding claim 13, Howson et al. teach a medication delivery device with a basis module and one or more modules wherein the replaceable modules cooperate with the basis module to provide a specific function, namely drug delivery.

Eggers et al. disclose a modular patient care system easy upgrades to adapt to future user needs (col. 2, lines 11-29). In an embodiment, Eggers et al. disclose the patient care device as having an interface unit or basis module 100 and one or more functional units or replaceable modules 150 wherein each replaceable module provides patient monitoring or therapy (col. 3, lines 7-9). Eggers et al. further disclose that each replaceable module may be a syringe pump, an infusion pumping unit, printer, temperature monitor, telemetry link, blood pressure monitor etc. (col. 4, lines 59-67) or a functional unit adapted for other uses.

The claimed functional modules are well known in the art.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided additional functional units as taught by Eggers et al. in the device of Howson et al. to adapt to changing user needs.

Method steps 16-18 and 20 are rendered obvious by the above discussion.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Howson et al. in view of Brown, further in view of Eggers et al.

Howson et al. do not disclose locking medication delivery device 11 to prevent separation of device 11 into its individual components.

Brown teaches a locking device in a drug delivery device 10 to hold a component of the device captive within the housing 11 of the device.

See discussion for claims 7 and 13.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a locking device to hold the various components of device 11 of Howson et al. as modified by the teachings of Eggers et al. captive within a housing as taught by Brown.

Method step 19 is rendered obvious by the above discussion.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5590648: Text.

US 6066243: Col. 4, col. 5, col. 6 and col. 7.

US 5935099: Text

US 6302855: Text.

US 5256157: Col. 3, col. 4 and col. 5.

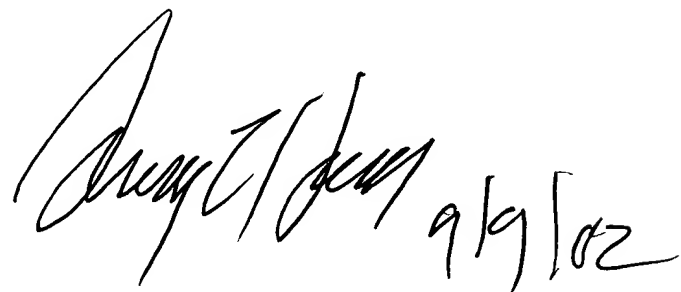
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached on 8:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Huson can be reached on (703) 308-2580. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0975.

AR

September 9, 2002

A handwritten signature in black ink, appearing to read "Gregory Huson", followed by the date "9/9/02".

GREGORY HUSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700